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Yoshihiro Nagaoka

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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/500,385	Applicant(s) NAGAOKA ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/31/2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8-10,13-16,23,24 and 26-29 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-5, 8-10, 13-16,23-24 and 26 is/are rejected.
- 7) ☒ Claim(s) 8-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendments and remarks dated 12/31/2008 have been acknowledged.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

3. The drawings remain objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the reagent containers having a dispensing mechanism, as is still recited in the instant claim(s), must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Election/Restrictions

4. Newly submitted claims 27-29 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The original claims 1, 4-5, 8-10, 13-16, 23-24 and 26 (Species I) are drawn to

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an extractor comprising a hole forming device and an extracting device having a capturing section connected to a plurality of reagent containers via a flow path, the flow path including a bent section which “at a particular stage prevents the flow of liquid from the reagent containers which are connected to the capturing sections, and at another stage, forms the liquid flow due to the centrifugal force from the rotation of the extracting device, the reagent containers being located closer to a center of rotation than the capturing section.

The newly submitted claims 27-29 (Species II) are drawn to a device comprising a main body; at least one analyzing disc mounted on the main body; a motor; a holding device rotatably supported by the motor; plural analyzers provided on the holding device; an operating device mounted on the main body; and a hole forming device for forming vent holes on the plural analyzers cover.

The only technical feature common for the above defined Species, is a hole forming device. This feature is well known in the art (see, for example, Figure 26 of Bedingham et al., US 20020047003, showing piercing tool 1349 configured for making holes in the cover / seal 1346 of the rotating structure 310. Thus, the hole forming device does not contribute any novelty over the prior art. Therefore, the unity of inventions is lacking. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 27-29 have been withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

5. Claims 8 and 9 are objected to under 37 CFR 1.75(c) as being in improper form because claim 8, as amended, depends on claim 8. See MPEP § 608.01(n).

Correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 4-5, 8-10 and 13-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1, 4-5, 10 and 15-16, as amended, recite a “structure body having an extracting device and a hole forming device, said structure body is supported so as to be rotatable”. Examiner found no support for this limitation in the original disclosure. While the specification and the drawings support the extracting device and the hole forming device being each configured for independent rotation, there is no support for the two components in question (which constitute a single “structure body”) to be rotated as a whole entity, as is currently recited.

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8. Claims 1, 4-5, 8-10, 13-16, 23-24 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 4-5, 10 and 15-16, as amended, do not set forth clear structural inter-relationships between the hole forming device and the rest of the elements of the instantly claimed invention. Additionally, the “side opposite to the rotation center side”, remains unclear since the claims do not define what the “rotation center side” is. Moreover, the recitation of the “side opposite to a rotation center side” followed by “namely an outer periphery side”, further increases the confusion (especially, in case a center of rotation is disposed outside the rotated structure). Note that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86

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USPQ 481 (Bd. App. 1949). In the present instance, the claims recite the broad recitation of the “side opposite to a rotation center side”, and the claims also recite the “outer periphery side”, which is a narrower limitation, in the given context.

See also claim 23.

In claim 5, “said periphery side of said capturing section”, lacks antecedent basis. See also claims 9-10 and 13.

In claim 8, the “reagent containers including washing solution containers”, remains unclear. See also claim 16.

In the amended claim 24, the “reagent outlet of said washing solution to be used an early timing is positioned a rotation center to the same extent”, is extremely unclear. It is also not clear what structural features would provide for the plurality of washing solutions being “respectively used at different timings” and how the recited functionality can be implemented without involvement of a controller.

Claim Rejections - 35 USC § 102

9. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as anticipated by Schembri (US 5,472,603).

Schembri discloses an analytical device comprising, as shown in Figure 2, rotatable structure 40 which includes capturing section 60, a plurality of containers 41, 42, 46, 64 [‘reagent, specimen, storage, mixing or washing solution containers’] having exit passage 62 [‘outlet’] and connected to the capturing section 60 via flow path 50. The

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flow path includes elbow siphon 53 ['bent section which returns to the rotation center side']. Depending on a speed of the rotor, the combination of centrifugal and capillary forces prevents or allows fluid flow along the fluid path, thus allowing to control the timing of the analysis process (see Col.3, lines 40-50).

Claim Rejections - 35 USC § 103

10. Claims 1, 4-5, 8-10, 13-16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schembri in view of Bedingham et al.

With respect to claims 1, 4-5, 8-10, 13-16, although Schembri discloses the micro fluidic structure being provided with means "for introducing fluid therein" the introduction of fluid "could be accomplished by any number of means known to the Artisan" ['dispensing mechanism' - see Col.4, lines 55 plus], the reference does not explicitly teach a dispenser or any other device specifically configured for making holes in the micro fluidic structure. However, this feature is known in the art. Bedingham discloses a rotational micro-fluidic structure 310, 410, 610 (Figures 9-10, 13) having a plurality of containers 350, 450, 650 covered by sealing layer 430, 630, 640. Figure 26 also shows a piercing tool 1349 configured for making holes in the cover / seal 1346 of the rotating structure 310. It would have been clearly within the ordinary skill of an artisan at the time the invention was made to have employed a sealing cover in the modified apparatus of Schembri, in order to provide clean environment for the test procedures. It would have been also within the ordinary skill to have equipped the modified apparatus of Schembri with a device configured to penetrate such cover, in order to gain more

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control over fluid flow by providing additional inlets or outlets / vents, when needed (depending on particular goals of the testing process).

Regarding claim 26, Schembri does not disclose an optical device configured to provide heating to the contents of the containers. Bedingham teaches i(see Figure 9 and [0141]) that the “individual chambers 350 can be selectively heated by suitable electromagnetic energy supplied by an electromagnetic energy source 370 [‘optical device’] that heats the materials in the process chambers 350”. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have employed similar heating means in the modified apparatus of Schembri, in order to precisely and selectively control the temperature of the fluids, because such heaters allow to deliver a selected amount of electromagnetic energy to selected process structures.

Response to Arguments

11. Applicant's arguments filed 12/31/2008 have been fully considered but they are not persuasive, or moot in view of the new ground of rejection.

Applicant argues that the “In the arrangement of Schembri...it is not possible for the liquid to flow properly because capillary fluidization cannot be generated”. Examiner notes that such functionality is not recited in the instant claims.

Applicant further argues that the “elbow (53) of Schembri is positioned at the innermost peripheral portion of the vessel. Consequently, liquid is prevented from flowing out even when the pressure in the vessel remains high. Furthermore, liquid

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is forced to pass through the siphon (50) in response to centrifugal force generated.

Since liquid reagents cannot flow properly in the device, Schembri utilizes bead-type reagents. Such an arrangement clearly differs from that of independent claim 16”.

Examiner maintains that the elbow 53 of Schembri clearly reads on the instant recitation of the “bent flow path portion which returns closer to a rotation center” than an outlet port of the containers.

Applicant also argues that, “according to Schembri, the vessels (41), (42), (46), and (60) are merely connected in series and there is no provision for independently controlling the use of the reagents”. Examiner insists that neither the independent “controlling the use of the reagents”, nor structural means capable of providing for such control (for example, a controller), are not recited in the instant claims.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/

Supervisory Patent Examiner, Art Unit 1797